UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

NORFOLK COUNTY RETIREMENT SYSTEM, Individually and On Behalf of All Others Similarly Situated,	Civ. No.
	CLASS ACTION
Plaintiff,	**COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS**
v.	
ST. JUDE MEDICAL, INC., DANIEL J. STARKS, JOHN C. HEINMILLER, DONALD J. ZURBAY, and ERIC S. FAIN,	DEMAND FOR JURY TRIAL
Defendants.	

Plaintiff Norfolk County Retirement System ("Norfolk County" or "Plaintiff") makes the following allegations based upon the investigation of Plaintiff's counsel, which included a review of U.S. Securities and Exchange Commission ("SEC") filings by St. Jude Medical, Inc. ("St. Jude" or the "Company"), as well as other regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities fraud class action brought by Norfolk County on behalf of itself and all other similarly situated persons or entities who, between October 19, 2011 and November 20, 2012, inclusive (the "Class Period"), purchased or otherwise

acquired the publicly-traded common stock of St. Jude (the "Class"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act") against St. Jude and certain of its officers.

2. This action alleges that Defendants made false and misleading statements, and concealed material information relating to the safety, durability, and manufacturing processes of certain cardiac rhythm management lead wires produced by the Company, specifically the Company's new generation of leads marketed under the name "Durata" ("Durata," or "Durata Leads").[1] As a result of these statements, Defendants caused the Company's shares to trade at artificially inflated prices, to the detriment of the Company's shareholders.

3. St. Jude derives a significant portion of its revenues and profits from sales of Durata Leads and the cardiac equipment that rely on Durata Leads. Even before the Class Period began, Defendants knew that the Company's previous generation of leads, marketed under the names "Riata" and "Quick," had suffered from significant design flaws in the composition and construction of their insulation. Because these flaws created a risk of possibly lethal electric shocks or tissue penetration, St. Jude had stopped marketing those products.

4. The Company claimed that these potentially lethal manufacturing defects had been resolved in its new line of Durata Leads by using an improved insulator called

[1] The Company's Durata Leads were formerly marketed under the name "Riata ST Optim." Prior to and during the Class Period, St. Jude manufactured and marketed two other relevant types of lead wires: (1) the Riata and Riata ST ("Riata Leads"); (2) QuickSite and QuickFlex ("Quick Leads").

"Optim," a co-polymer of silicone and polyurethane approved by the U.S. Food and Drug Administration (the "FDA") in 2006.

5. As early as October 19, 2011, Defendants made positive statements about the safety and efficacy of Durata Leads despite being aware that they suffered similar design flaws and presented similar risks to Riata and Quick Leads due to substantial flaws in the Durata Lead design, production, and quality control processes. Defendants misled investors by consistently presenting Durata as a well-researched, well-designed improvement to the Riata Lead design, statements that led investors to push St. Jude's share prices higher.

6. As a result of Defendants' false and misleading statements and omissions, St. Jude's common stock traded at artificially inflated prices during the Class Period.

7. On October 17, 2012, St. Jude surprised investors by disclosing that the Company foresaw a significant risk of receiving a warning letter from the FDA as a result of a then-ongoing inspection of a St. Jude manufacturing facility involved in the production of leads. The market reacted negatively to this news, causing St. Jude's stock price to fall by $2.09 per share, or 4.87 percent, to close at $40.85 per share following trading on October 17, 2012.

8. Despite this revelation, the Company's Chief Executive Officer ("CEO") Daniel J. Starks ("Starks") reassured investors on a conference call that day that "across the board with the pacemaker product line, with the ICD product line, [and] with the Durata and Riata ST Optim product line . . . the reliability data and the evidence that that implies for the robustness of our quality systems is all very good."

9. When St. Jude published a heavily redacted version of the FDA's report on the manufacturing facility a week later, the Company affirmed that "none of the observations identified a specific issue regarding the clinical or field performance of any particular device." In reaction to this news, St. Jude's stock price fell by $1.44 per share, or 3.63 percent, to close at $38.27 per share on elevated trading volume during the following trading session on October 25, 2012.

10. Ultimately, on November 20, 2012, the FDA released a less-redacted version of the report detailing the results of its inspection of St. Jude's manufacturing facility that revealed that the Company suffered from significant and systemic flaws in the Durata Lead design, production, and quality control processes.

11. The following true facts were known to or recklessly disregarded by the Defendants but concealed from St. Jude's shareholders during the Class Period: (1) Durata Leads were subject to the same or similar design flaws that had led to abrasion and wire exposure risks in Riata and Quick Leads; (2) the Company's design, manufacturing, testing, and quality control processes for leads, including Durata Leads, was flawed by such significant deficiencies—including the disregard of St. Jude's own quality control policies that effectively bypassed 80 percent of certain design element tests—that the Company's leads presented a material risk to patients and would not be a commercial success; and (3) as a result of the foregoing, St. Jude lacked a reasonable basis to tout the testing and manufacturing processes underlying Durata and Optim, to characterize its Durata Leads as an improvement over its previous generation of leads, and to project that Durata Leads would be a commercial success.

12. Defendants' false and misleading statements and omissions caused St. Jude's stock to trade as high as $44.80 per share during the Class Period, and to close as high as $44.54 per share on March 27, 2012.

13. After the markets' close on November 20, 2012, the truth about the Company's manufacturing process for Durata Leads was revealed. Over the course of the trading session that followed on November 21, 2012, St. Jude's share price fell by $4.34 per share, or 12.15 percent, to close at $31.37 per share on extremely heavy trading volume.

JURISDICTION AND VENUE

14. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§ 78j(b) and 78t(a)] and SEC Rule 10b-5 promulgated thereunder [17 C.F.R. § 240.10b-5].

15. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 28 U.S.C. § 1331 [15 U.S.C. § 78a(a)].

16. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 28 U.S.C. § 1391(b), because many of the events and omissions complained of herein occurred in substantial part in the District of Minnesota.

17. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

18. Plaintiff Norfolk County purchased the publicly-traded common stock of St. Jude at artificially inflated prices during the Class Period, as set forth in the accompanying Certification and incorporated by reference herein, and has been damaged thereby.

19. Defendant St. Jude is a Minnesota corporation with headquarters in St. Paul, Minnesota. The Company's stock is listed on the New York Stock Exchange (the "NYSE") under the ticker symbol "STJ."

20. Defendant Daniel J. Starks is the President and CEO of St. Jude. CEO Starks certified the accuracy of the Company's quarterly filings with the SEC. Further, CEO Starks was responsible for materially false and misleading statements made, among other times, during the Company's scheduled earnings conference calls during the Class Period.

21. Defendant John C. Heinmiller ("Heinmiller") is an Executive Vice President of St. Jude. Prior to August 2012, Heinmiller concurrently served as the Company's Chief Financial Officer ("CFO"). In his capacity as CFO, Heinmiller certified the accuracy of the Company's quarterly filings with the SEC. Further, Heinmiller was responsible for materially false and misleading statements made, among other times, during the Company's scheduled earnings conference calls.

22. Defendant Donald J. Zurbay ("Zurbay") is St. Jude's CFO. Prior to August 2012, Zurbay served as the Company's Corporate Controller. In his capacity as CFO, Zurbay certified the accuracy of the Company's quarterly filings with the SEC.

23. Defendant Eric S. Fain ("Fain") is the President of the St. Jude's Implantable Electronic Systems Division. Prior to August 2012, Fain was the President of the Company's Cardiac Rhythm Management Division. Fain is responsible for materially false and misleading statements made, among other times, during the Company's scheduled earnings conference calls.

24. The Defendants named in paragraphs 20 through 23 are referred to as the "Individual Defendants."

25. During the Class Period, the Individual Defendants, as senior executive officers of St. Jude, were privy to confidential and proprietary information concerning St. Jude, its operations, safety and regulatory data, and information related to the ongoing quality control processes within the Company. The Individual Defendants also had access to material-adverse, non-public information concerning St. Jude, as discussed in detail below. Because of their positions with St. Jude, the Individual Defendants had access to non-public information about the Company's business, safety, quality control, and regulatory information through access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and/or board of directors meetings and committees thereof, and through reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew, or recklessly disregarded, that the adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public.

26. The Individual Defendants are liable as direct participants in the wrongs complained of herein. In addition, the Individual Defendants, by reason of their status as senior executive officers and/or directors, were "controlling persons" within the meaning of Section 20(a) of the Exchange Act, and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants were able to, and did, directly or indirectly, control the conduct of St. Jude's business.

27. The Individual Defendants, because of their positions with the Company, controlled and/or possessed the authority to control the contents of St. Jude's reports, press releases, and presentations to securities analysts and, through them, to the investing public. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading, prior to or shortly after their issuance, and had the ability and opportunity to prevent their issuance or cause them to be corrected. Thus, the Individual Defendants had the opportunity to commit the fraudulent acts alleged herein.

28. As senior executive officers and as controlling persons of a publicly-traded company whose common stock is registered with the SEC, traded on the NYSE, and governed by the federal securities laws, the Individual Defendants had a duty to promptly disseminate accurate and truthful information with respect to the safety, quality control, regulatory oversight, and outlook of the Company's products, and to correct any previously issued statements that had become materially misleading or untrue so that the market price of St. Jude's common stock would be based upon truthful and accurate

information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

FRAUDULENT CONDUCT AND COURSE OF BUSINESS

29. Defendants are liable for: (1) making false statements; or (2) failing to disclose adverse facts known to them about St. Jude. Defendants' deception was a success, as it: (1) misled the investing public regarding St. Jude's prospects and business; (2) artificially inflated the prices of St. Jude common stock; and (3) caused Plaintiff and other members of the Class to purchase St. Jude's common stock at inflated prices.

SUBSTANTIVE ALLEGATIONS

Background

30. St. Jude is a global medical device company with more than 20 operational sites and manufacturing facilities, employing thousands of people worldwide. The Company develops and manufactures a number of lines of products, including cardiac rhythm management ("CRM") systems. CRM systems include both pacemakers and implantable cardioverter-defibrillators ("ICDs"). ICDs are designed to treat arrhythmia, a potentially life-threatening condition in which a patient's heart rhythm becomes irregular.

31. The Company's CRM systems rely on leads, thin wires that extend through the body connecting the ICD to the heart and allow the ICD to monitor the heart's rhythm and provide corrective electrical pulses in the event of arrhythmia. Leads must be properly insulated to prevent: (1) improper shocks due to contact with surrounding body fluid and tissue; and (2) harmful piercing of surrounding tissues—particularly heart

tissue—by the leads' metal wires, should they become exposed. Either event may pose a life-threatening risk.

32. As stated in St. Jude's annual report for 2011 filed with the SEC on Form 10-K on February 29, 2012, "[a] significant portion of [St. Jude's] net sales [are] relate[d] to CRM devices . . . ."

33. The market for CRM devices and leads in the United States is highly competitive and is served by a handful of manufacturers that vie for physicians' loyalty. During 2011, St. Jude commanded approximately 25 percent of the U.S. market share for CRM devices.

34. During the periods relevant to this action, St. Jude manufactured and marketed leads with two types of insulation: (1) silicone insulation (used in Riata and Quick Leads); and (2) a proprietary combination of polyurethane and silicone insulation called "Optim" (used in Durata Leads).

35. At least as early as October 2005, St. Jude was aware that the Riata Leads, had shown signs of problems relating to abrasion of that model's silicone insulation. Between 2006 and 2008, the Company conducted an audit of insulation breaches, concluding that leads with silicone insulation were subject to serious insulation-related problems, including so-called "inside-out" abrasion. Beginning in 2008, the FDA began requiring CRM lead manufacturers to conduct post-market studies of defibrillator leads.

36. The Durata Leads were intended to be the Company's next generation lead, replacing Riata, with Optim composite insulation providing improved abrasion resistance.

37. On December 15, 2010, St. Jude published an open letter to physicians announcing that Riata Leads suffered from a "protrusion" or "externalization" problem, in which wires could emerge from the insulation, and that the Company would discontinue all further sales of Riata Leads. The Company recommended that doctors continue regular monitoring of patients with Riata Leads and perform specific tests if a flaw was suspected. This letter claimed that Riata Leads had demonstrated a 0.47 percent rate of insulation abrasion over nine years and failed to disclose that the insulation failures of Riata Leads could lead to life-threatening problems.

38. Prior to the markets' open on January 26, 2011, St. Jude issued a press release reporting its results of operations for the three months and one year ending January 1, 2011. In relation to the Company's CRM operations, the report specifically touted double-digit growth in St. Jude's ICD revenues.

39. After the close of the markets on March 2, 2011, St. Jude filed its annual report on Form 10-K for the Company's 2010 fiscal year ended January 1, 2011 with the SEC. As part of its filing, the Company discussed its Durata Leads, a design that the Company claimed employed insulation formulated to address issues of insulation abrasion, noting that "[t]he Durata leads, along with the Riata ST Optim leads . . . feature our exclusive Optim insulation material that combines the durability of polyurethane and the softness of silicone." St. Jude further claimed that "Optim insulation has demonstrated a statistically significant reduction in the incidence of insulation abrasion when compared to our previous silicone insulated leads."

Defendants' False and Misleading Statements Issued During the Class Period

40. Prior to the opening of the markets on October 19, 2011, St. Jude issued a press release announcing its financial results for the third quarter of 2011. In connection with this report, St. Jude hosted a conference call with investors and analysts, during which CEO Starks made positive statements about the Company's manufacturing and research processes for its ICD leads, including:

> [W]e have the most robust active reporting, active follow-up of our device reliability including our ICD lead reliability. . . . We conduct additional studies as needed on an active basis. . . . [W]e break out more data and that the inputs into our data are far more comprehensive and robust than is the case for other organizations. So we have a lot of confidence that we have a good handle on St. Jude medical device reliability.

41. CEO Starks further made statements about the reliability of Optim and St. Jude's competitive advantages with regard to ICD leads:

> Optim is 50 times more resistant to abrasion than silicon[e].
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> * * *
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> We like talking about the competitive advantage of St. Jude Medical's ICD leads and pacing leads. We like talking about the advantages of the reliability data. We like talking about the advantages of our lead handling performance. We like talking about the advantages of our smaller leads without any compromise in insulation and in fact with a superior technology in our insulation material. So that's what's teed up here.
>
> I've offered you a couple of my comments and, again, the engineering data is really very robust, very favorable to St. Jude Medical, very favorable to patient safety and our entire lead line is then a strong basis for our gaining market share over the last four years and it will continue to be a basis for our gain of share in the de novo market here in years to come.

42. Near the end of the trading day on November 9, 2011, the Company filed its quarterly report on Form 10-Q for the quarter ended October 1, 2011 with the SEC. This report included information substantially similar to that reported in the Company's October 19, 2011 press release. The report failed to offer investors any qualifying or corrective information relating to Riata, Quick, or Durata Leads, or the Company's design, manufacturing, testing, or quality control processes.

43. The Company's November 9, 2011 Form 10-Q included a certification signed by CEO Starks, incorporated therein as Exhibit 31.1, which stated:

> I, Daniel J. Starks, certify that:
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> 1. I have reviewed this quarterly report on Form 10-Q of St. Jude Medical, Inc.;
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> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
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> 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
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> 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
>
> > a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant,

including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a

> significant role in the registrant's internal control over financial reporting.

44. The Company's November 9, 2011 Form 10-Q further included a substantially similar certification signed by then-CFO Heinmiller as Exhibit 31.2.

45. On November 28, 2011, St. Jude published a second open letter to physicians (the "2011 Letter") related to Riata Leads.[2] The 2011 Letter set forth updated results of the Company's ongoing review of Riata Leads, stating that "the incidence rate based on returns and complaints [for Riata Leads] is now estimated to be 0.63% for all cause abrasion versus the prior rate of 0.47% communicated in December 2010 . . . ." The Company also used the 2011 Letter to draw distinctions between the failed Riata and the superior Durata Leads and their Optim insulation, characterizing the difference in "the incidence of externalized conductors between Riata silicone leads and Durata Optim insulated leads (0.10% vs. none)" as "highly statistically significant . . . ."

46. After the markets closed on December 15, 2011, St. Jude issued a press release disclosing that the FDA had classified the 2011 Letter as a Class I Recall. The FDA defines a Class I Recall—the most serious type—as "a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."

47. Prior to the market opening on January 25, 2012, St. Jude issued a press release reporting its results of operations for the three months and one year ended

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[2] *See* Letter from Mark Carlson & Philip Tsung to Physicians, Medical Device Advisory Important Product Information Update, Nov. 28, 2011, *available at* http://www.riatacommunication.com/us.aspx.

December 31, 2011. The report noted a six percent drop in the Company's ICD revenue as part of its discussion of the Company's CRM operations.

48. In connection with the earnings release, the Company hosted a conference call with investors and analysts that day. During the question-and-answer session, Defendant Fain made positive statements about the performance of the Company's Optim leads and the Company's commitment to gathering data about its Optim leads:

> [W]hat we're focused on is really about the data and making sure that we have very good complete comprehensive data on the performance of our Optim leads and in particular on in our Durata lead. And we're going to be doing that going forward.
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> * * *
>
> [W]e'll make it more visible going forward. But thus far that data supports as strong as anything anybody can talk about the overall excellent performance of Durata by any measure.

49. Following the markets' close on February 29, 2012, St. Jude filed its annual report for the three months and full year ending December 31, 2011, on Form 10-K with the SEC, which set forth information substantially similar to that included in the January 25, 2012 press release. The Company's February 29, 2012 Form 10-K included certifications substantially similar to those described in paragraphs 43 and 44.

50. On April 4, 2012, before the markets opened, St. Jude issued a press release disclosing that the Company's Quick Leads were subject to the same hazards of protruding wires as the previously-recalled Riata Leads and that St. Jude would no longer sell Quick Leads. Quick Leads employed the same silicone insulation that the Company knew to be subject to failure from abrasion since 2010.

51. On the morning of April 18, 2012, St. Jude issued a press release discussing its operating results for the three-month period ending March 31, 2012. The Company reported revenues from ICD sales of $450 million, or 32.26 percent of St. Jude's total net revenues for the quarter. In connection with the press release, CEO Starks stated in part: "First quarter results exceeded expectations for sales and adjusted earnings per share. This was driven especially by innovations designed to improve patient outcomes and reduce the cost of health care such as our new line of Unify Quadra ICDs in the U.S." St. Jude's Unify Quadra ICD employs the same Optim insulation as Durata Leads.

52. In connection with the earnings announcement, St. Jude hosted a conference call for investors and analysts. During this call, Defendant Fain responded to a question related to the durability of Optim, stating in relevant part:

> [T]he Optim insulation has shown extremely great, I think very strong abrasion resistance both on the bench, both in our clinical performance. . . . We haven't seen anything in terms of externalized conductors over the lead body itself which is made out of the polyurethane material.
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> So I think we have plenty of good evidence and good experience to be able to have confidence that that really is the answer. We've also looked at return leads with Optim and have seen no signs at all of any wear or abrasion in the distal segments of those leads. So everything—all the information that we have available to us and with good numbers and with bench data supporting our clinical experience points to design changes really mitigating that issue.

53. During the afternoon on May 3, 2012, St. Jude filed its quarterly report on Form 10-Q with the SEC for the three-month period ending March 31, 2012. The Company's report failed to disclose the ongoing problems with the design, testing, and

quality control of Durata Leads. The report further failed to disclose that on May 2, 2012, an adverse event report had been filed with the FDA by a physician describing an externalization event in which Durata Leads had broken through their insulation, requiring removal. The Company's May 3, 2012 Form 10-Q included certifications substantially similar to those described in paragraphs 43 and 44.

54. On June 12, 2012, news outlets disclosed the May 2, 2012 FDA report describing the Durata externalization event.

55. Prior to the market opening on July 18, 2012, St. Jude issued a press release reporting its results of operations for the three-month period ending June 30, 2012. The Company reported revenues from ICD sales of $459 million, or 32.55 percent of St. Jude's total net revenues for the quarter.

56. Following the markets' close on August 7, 2012, St. Jude filed its quarterly report on Form 10-Q with the SEC for the three-month period ending June 30, 2012, which set forth information substantially similar to that included in the July 18, 2012 press release. The Company's report failed to disclose the ongoing problems with the design, testing, and quality control of Durata Leads. The Company's August 7, 2012 Form 10-Q included certifications substantially similar to those described in paragraphs 43 and 44.

The Truth About St. Jude's Deficient
Manufacturing and Quality Control Processes Begins to Emerge

57. On September 25, 2012, the FDA initiated an inspection of the Company's manufacturing facility in Sylmar, California, which produces, among other things, the

Durata Leads. The inspection continued through October 17, 2012, and at the inspection's conclusion, the FDA issued St. Jude a letter with eleven inspection observations on a Form 483 (the "Form 483 Letter"). The Form 483 Letter outlined serious failures in St. Jude's design, manufacturing, testing, and quality control procedures, specifically with regard to Durata Leads.

58. Prior to the markets' open on October 17, 2012, St. Jude issued a press release regarding its operating results for the third quarter of 2012. In relation to the Company's CRM business, the report stated:

> Total CRM sales, which include implantable cardioverter defibrillator (ICD) and pacemaker products, were $691 million for the third quarter of 2012, an 8 percent decrease compared with the third quarter of 2011. Total CRM sales for the third quarter decreased 4 percent after adjusting for the impact of foreign currency.
>
> Of that total, ICD product sales were $412 million in the third quarter, a 7 percent decrease compared with the third quarter of 2011. On a constant currency basis, total ICD sales declined 4 percent from the prior year.
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> Third quarter pacemaker sales were $279 million, a 9 percent decrease compared to the third quarter of 2011. After adjusting for the impact of foreign currency, pacemaker sales decreased 4 percent.
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> * * *
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> In the third quarter of 2012 the Company recorded after-tax charges of $80 million, or $0.25 per share primarily related to organizational realignment actions announced this quarter as well as our previously announced actions initiated during the second quarter of 2011 to realign certain activities within its CRM business.

The report made no mention of the FDA inspection at the Sylmar facility.

59. In connection with the earnings release, the Company hosted a conference call with investors and analysts. As part of an extensive prepared statement, CEO Starks discussed "product reliability" for the Company's CRM leads, including the statement:

> The global advisories involving our Riata and Riata ST silicone leads have drawn extensive attention from FDA. We believe that this attention is appropriate, and are cooperating fully with FDA. FDA is currently inspecting our CRM facility in S[yl]mar, California. Although this inspection has not yet concluded, we believe it will likely end with observations on a Form 483. We would not be surprised if these observations are ultimately followed by issuance of a warning letter. If either of these events occur, we will respond in a way which demonstrates that our top priorities are patient safety and quality assurance. In the meantime, we want investors to be assured that we are taking all appropriate regulatory circumstances into account in managing our business and in setting investor expectations moving forward.
>
> Next, I would like to offer an update on the performance of our Riata ST Optim and our Durata lines of high-voltage leads. Neither of these product lines has been the subject of a safety advisory or a product recall. Over 85% of Durata lead components are newly designed and have resulted in improvements in abrasion resistance and reduction in all cause malfunction. Our post-market surveillance of Riata ST Optim and Durata high-voltage leads is far more robust than our surveillance of Riata silicone leads due to our initiation of three actively managed registries . . . .

60. Analysts participating in the conference call were openly surprised, repeatedly returning to the prospect of the Company receiving a Form 483 and a warning letter from the FDA. In particular, analysts expressed confusion as to why CEO Starks would make such a statement both before the inspection was complete and without any independent knowledge (as Starks disclaimed) of problems that required specific disclosure.

61. The market reacted negatively to this news, causing St. Jude's stock price to fall by $2.09 per share, or 4.87 percent, to close at $40.85 per share following trading on October 17, 2012.

62. Then, after the markets closed on October 24, 2012, St. Jude filed a Form 8-K with the SEC providing information about the FDA's inspection of the Sylmar facility and attaching a heavily redacted copy of the Form 483 Letter as Exhibit 99.1. St. Jude claimed to have redacted the Form 483 Letter "based on its good faith interpretation of Freedom of Information Act (FOIA) exemption (b)(4), which protects confidential and proprietary information from disclosure." Describing the results of the inspection, the Company emphasized that "none of the observations identified a specific issue regarding the clinical or field performance of any particular device."

63. In reaction to this news, St. Jude's stock price fell by $1.44 per share, or 3.63 percent, to close at $38.27 per share on elevated trading volume during the following trading session on October 25, 2012.

64. On November 7, 2012, St. Jude filed its quarterly report on Form 10-Q with the SEC for the three-month period ending September 29, 2012. The Company's report confirmed the receipt of the Form 483 Letter and reiterated Defendants' prior statements regarding the FDA inspection of the Company's Sylmar facility, stating in relevant part:

> In late September 2012, the FDA commenced an inspection of the Company's Sylmar, California facility, and, following such inspection, issued eleven observations on a Form 483. In early November 2012, the Company's CRM division provided written responses to the FDA detailing proposed corrective actions and immediately initiated efforts to address FDA's observations of nonconformity. None of the FDA

> observations identified a specific issue regarding the clinical or field performance of any particular device. The Sylmar, California facility will continue to manufacture CRM devices while the Company works with the FDA to address these observations.

65. The Company's November 7, 2012 Form 10-Q included a certification substantially similar to that described in paragraph 43, as well as a certification by CFO Zurbay, the content of which was substantially similar to that made by EVP Heinmiller, as described in paragraph 44.

The Truth About Durata Leads Is Revealed

66. After the markets' close on November 20, 2012, the FDA released its own version of the Form 483 Letter, which—unlike the version released by the Company on October 24, 2012—did not redact the names of the product in question in each observation. Rather, the FDA's version of the Form 483 Letter made clear that the numerous concerns raised by the FDA's inspection of the Company's Sylmar plant almost universally pertained to the design, production, and quality control for the manufacturing process of Durata Leads.

67. Contrary to the Company's earlier assertions surrounding the safety and reliability of Durata and the content of the Form 483 Letter, the FDA version of the Form 483 Letter revealed that the Sylmar facility had numerous and long-running design, production, and quality control problems that affected Durata Leads. Among other things, the Form 483 Letter noted that St. Jude:

(a) failed to validate three of the test methods intended to verify the design inputs related to Durata;

(b) failed to follow its own written test procedures requiring each lead to be tested five times, when in fact, St. Jude tested each lead only once;

(c) relied upon Durata design risk analysis with material flaws, including a failure to evaluate certain study results;

(d) relied upon an inadequate Durata design risk analysis, which improperly combined recalled and non-recalled devices;

(e) failed to maintain a proper Durata design history file, rendering unclear when the Company approved Durata design inputs, outputs, verification, validation, and design transfer, and when the Company conducted its final approval of the Durata design, despite 6 days of inspection requests;

(f) failed to maintain an adequate corrective action and preventive action system, which led to (among other problems) inadequate corrective action relating to Silicone Leads; and

(g) failed to maintain an adequate complaint response program, which led to a failure to determine whether an investigation into a Durata-related complaint was necessary, including internally conflicting data.

68. In reaction to this news, St. Jude's stock price fell $4.34 per share, or 12.15 percent, to close at $31.37 per share on November 21, 2012, on extremely heavy trading volume.

69. Defendants lacked a reasonable basis for their positive statements regarding the design, manufacturing, testing, and reliability of Durata Leads during the Class Period. The following true facts were known to or recklessly disregarded by the

Defendants but concealed from St. Jude's shareholders during the Class Period: (1) Durata Leads were subject to the same or similar design flaws that had led to abrasion and wire exposure risks in Riata and Quick Leads; (2) the Company's design, manufacturing, testing, and quality control processes for leads, including Durata Leads, were flawed by such significant deficiencies—including the disregard of St. Jude's own quality control policies that effectively bypassed 80 percent of certain design element tests—that the Company's leads presented a material risk to patients and would not be a commercial success; and (3) as a result of the foregoing, St. Jude lacked a reasonable basis to tout the testing and manufacturing processes underlying Durata and Optim, to characterize its Durata Leads as an improvement over its previous generation of leads, and to project that Durata Leads would be a commercial success.

SCIENTER

70. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made or acted with reckless disregard for the true information known to them at the time for the reasons discussed above. In so doing, Defendants committed acts, and practiced and participated in a course of business that operated as a fraud or deceit on purchasers of St. Jude common stock during the Class Period.

LOSS CAUSATION/ECONOMIC LOSS

71. During the Class Period, as detailed herein, Defendants made false and misleading statements that artificially inflated the price of St. Jude common stock, and

operated as fraud or deceit on Class Period purchasers of St. Jude common stock by misrepresenting the recent and ongoing decline in the Company's net sales, competitive position, and business prospects. Later, when Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of St. Jude common stock fell precipitously as the prior artificial inflation came out of the price. As a result of their purchases of St. Jude common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

NO SAFE HARBOR

72. St. Jude's verbal "Safe Harbor" warnings that accompanied its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

73. Defendants are also liable for any false FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false, and the FLS was authorized and/or approved by an executive officer of St. Jude who knew that the FLS was false. None of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to, or stated to be dependent on, those historic or present tense statements when made.

APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

74. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) the Company's stock traded in an efficient market;

(d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

(e) Plaintiff and other members of the Class purchased St. Jude common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

75. At all relevant times, the markets for St. Jude stock were efficient for the following reasons, among others:

(a) as a regulated issuer, St. Jude filed periodic public reports with the SEC;

(b) St. Jude regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and other wide-ranging

public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services; and

(c) St. Jude common stock was actively traded in an efficient market, namely the NYSE, under the symbol "STJ."

76. Plaintiff is also entitled to the presumption of reliance to the extent that Defendants' statements concerning the FDA inspection of St. Jude's Sylmar, California facility failed to disclose material facts.

CLASS ACTION ALLEGATIONS

77. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure ("Rule 23") on behalf of the Class. Excluded from the Class are Defendants, directors and officers of St. Jude, and their families and affiliates.

78. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. As of November 6, 2012, St. Jude had 308,177,250 shares of common stock outstanding, owned by thousands of investors.

79. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions that may affect individual Class members include:

(a) whether Defendants violated the Exchange Act;

(b) whether Defendants omitted and/or misrepresented material facts;

(c) whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether Defendants knew or recklessly disregarded that their statements were false and misleading;

(e) whether the price of St. Jude common stock was artificially inflated; and

(f) the extent of damage sustained by Class members and the appropriate measure of damages.

80. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct.

81. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.

82. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

COUNT I

For Violation of § 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

83. Plaintiff incorporates paragraphs 1 through 82 by reference.

84. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading

in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

85. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices, and a course of business that operated as fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of St. Jude common stock during the Class Period.

86. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially-inflated prices for St. Jude common stock. Plaintiff and the Class would not have purchased St. Jude common stock at the prices they paid, or at all, had they been aware that the market prices were artificially and falsely inflated by Defendants' misleading statements.

87. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of St. Jude common stock during the Class Period.

COUNT II

For Violation of § 20(a) of the Exchange Act
Against the Individual Defendants

88. Plaintiff incorporates paragraphs 1 through 87 by reference.

89. The Individual Defendants acted as controlling persons of St. Jude within the meaning of Section 20(a) of the Exchange Act. By virtue of their positions and their power to control public statements about St. Jude, the Individual Defendants had the power and ability to control the actions of St. Jude and its employees. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Declaring this action to be a proper class action pursuant to Rule 23;

B. Awarding Plaintiff and the members of the Class damages and interest;

C. Awarding Plaintiff's reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: December 10, 2012

Respectfully submitted,

s/ Lindsey A. Davis

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Counsel for Plaintiff
Norfolk County Retirement System

CERTIFICATION

I, Joseph Connolly, as Treasurer of Norfolk County Retirement System ("Norfolk County"), hereby certify as follows:

1. I am fully authorized to enter into and execute this Certification on behalf of Norfolk County. I have reviewed a complaint prepared against St. Jude Medical, Inc. ("St. Jude") alleging violations of the federal securities laws;

2. Norfolk County did not purchase securities of St. Jude at the direction of counsel or in order to participate in any private action under the federal securities laws;

3. Norfolk County is willing to serve as a lead plaintiff in this matter, including providing testimony at deposition and trial, if necessary;

4. Norfolk County's transactions in St. Jude during the Class Period are reflected in Exhibit A, attached hereto;

5. Norfolk County sought to serve as a lead plaintiff in the following class actions filed under the federal securities laws during the last three years:

In re DG FastChannel, Inc Securities Litigation, No. 10-cv-6523 (S.D.N.Y.)
In re Wilmington Trust Securities Litigation, No. 10-cv-0990 (D. Del.)
Pipefitters Local No. 636 Defined Benefit Plan v. Tekelec, No. 11-cv-0004 (E.D.N.C.)
In re Longtop Financial Technologies Ltd. Securities Litigation, No. 11-cv-3658 (S.D.N.Y.)
Greenberg v. Cooper Cos., Inc., No. 11-cv-5697 (N.D. Cal.)
In re Health Management Associates, Inc., Newsome, Curry & Farnham, No. 12-cv-46 (M.D. Fla.); No. 12-cv-163 (M.D. Fla.)
Norfolk County Retirement System v. Tempur-Pedic International Inc., No. 12-cv-195 (E.D. Ky.)

6. Norfolk County is currently serving as a lead plaintiff in the following class actions filed under the federal securities laws during the last three years:

Pipefitters Local No. 636 Defined Benefit Plan v. Tekelec, No. 11-cv-0004 (E.D.N.C.)
In re Health Management Associates, Inc., Newsome, Curry & Farnham, No. 12-cv-46 (M.D. Fla.); No. 12-cv-163 (M.D. Fla.)
Norfolk County Retirement System v. Tempur-Pedic International Inc., No. 12-cv-195 (E.D. Ky.)

7. Beyond its pro rata share of any recovery, Norfolk County will not accept payment for serving as a lead plaintiff on behalf of the class, except the reimbursement of such reasonable costs and expenses including lost wages as ordered or approved by the Court.

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct this 10 day of December, 2012.

Joseph Connolly
Treasurer of Norfolk County Retirement System